Reference number(s)
2234-A

SPECIALTY GUIDELINE MANAGEMENT

POMALYST (pomalidomide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Treatment of multiple myeloma, in combination with dexamethasone, in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of their last therapy
2. Treatment of adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in adult patients with KS who are HIV-negative

B. Compendial Uses
1. Systemic light chain amyloidosis
2. Primary central nervous system lymphoma

Refer to section II, Criteria for Initial Approval, for additional approvable regimens

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Multiple myeloma

Authorization of 12 months may be granted for the treatment of multiple myeloma when all of the following criteria are met:
1. The member has previously received at least two prior therapies for multiple myeloma including an immunomodulatory agent and proteasome inhibitor.
2. The requested medication will be used in one of the following regimens:
   i. In combination with daratumumab and dexamethasone
   ii. In combination with elotuzumab and dexamethasone
   iii. In combination with ixazomib and dexamethasone
   iv. In combination with bortezomib and dexamethasone
   v. In combination with carfilzomib and dexamethasone
   vi. In combination with cyclophosphamide and dexamethasone
   vii. In combination with isatuximab-irfc and dexamethasone
   viii. In combination with dexamethasone
   ix. As a single agent

B. Systemic light chain amyloidosis

Authorization of 12 months may be granted for the treatment of relapsed or refractory systemic light chain amyloidosis in combination with dexamethasone.

C. Kaposi Sarcoma

Authorization of 12 months may be granted for the treatment of Kaposi sarcoma when either of the following criteria are met:

1. Will be used in combination with antiretroviral therapy for the treatment of AIDS-related Kaposi sarcoma
2. Member is HIV-negative

D. Primary central nervous system lymphoma

Authorization of 12 months may be granted for the treatment of relapsed or refractory primary central nervous system lymphoma as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Pomalyst [package insert]. Summit, NJ: Celgene Corporation; May 2020.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 11, 2020.
3. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 1.2019) © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 25, 2019.
4. The NCCN Clinical Practice Guidelines in Oncology® Systemic Light Chain Amyloidosis (Version 1.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed March 25, 2019.
5. The NCCN Clinical Practice Guidelines in Oncology® AIDS-Related Kaposi Sarcoma (Version 1.2018) © 2018 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed March 25, 2019.
6. Sarclisa [package insert]. Bridgewater, NJ: Sanofi-aventis; March 2020.